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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,069	07/14/2006	Torsten Almen	Q90475	6111
23373 7590 03/22/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER SCOTT, ANGELA C				
ART UNIT		PAPER NUMBER		
1796				
NOTIFICATION DATE		DELIVERY MODE		
03/22/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
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### Office Action Summary

**Application No.**

10/552,069

**Applicant(s)**

ALMEN ET AL.

**Examiner**

Angela C. Scott

**Art Unit**

1796

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-11 and 13-42 is/are pending in the application.
- 4a) Of the above claim(s) 18-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-11, 13-17 and 42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date 1/14/2010
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants response of November 13, 2009 has been fully considered. Claims 4, 9-11, 13, 15-17 and 42 have been amended and claims 2, 3, and 12 are canceled. Claims 1, 4-11, and 13-42 are pending with claims 18-41 withdrawn from consideration.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-11, 13-17 and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that "at least one of the portions comprises a dissolved non-polymerizable organoiodine compound." The term "dissolved" would seem to imply that the organoiodine compound could only be present in the liquid portion and not the particulate portion. However, the claim states that it may be in either portion so it is vague and indefinite. Moreover, the specification gives no guidance on this issue. Therefore, for the purpose of further examination, this limitation will be interpreted to mean that the organoiodine compound may be present in either portion and that once these portions are mixed, it will become dissolved in them.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Lidgren (US 6,586,009).

Regarding claims 1 and 5, Lidgren teaches a bone cement containing a liquid component containing a polymerizable substance and a powder component containing a plastic substance

and an X-ray contrast medium (Abstract), such as iohexol (a non-polymerizable organoiodine compound) (Col. 2, lines 65-67).

Regarding claim 6, Lidgren teaches that an antibiotic compound is added to the composition (Example 4).

Regarding claims 16 and 17, Lidgren teaches that the polymer particles of the particulate polymer portion have a particle size of around 80-100  $\mu\text{m}$  (Example 1). Since the particle size of the polymer varies between 80 and 100 microns, it is polydisperse.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 9-11 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009) as applied to claim 1 above.

Lidgren teaches the bone cement according to claim 1. Lidgren additionally teaches that the liquid and powder components are adapted to be mixed and thereby provide a setting mass which is set to form the cement (Col. 2, lines 50-55). The Office takes Official Notice that one of ordinary skill in the art would mix these components until they are homogeneously distributed, meaning that the chemical substances are present in both components in

concentrations that differ by less than 50%, most preferably by less than 10%, in order to provide the advantages of this composition.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009) in view of Posey-Dowty et al. (US 5,258,420).

Lidgren teaches a bone cement containing a liquid component containing a polymerizable substance and a powder component containing a plastic substance and an X-ray contrast medium (Abstract), such as iohexol (a non-polymerizable organoiodine compound) (Col. 2, lines 65-67). Lidgren additionally teaches that an antibiotic compound is added to the composition (Example 4).

Lidgren does not teach that the antibiotic compound is specifically in the form of a lipophilic ester such as erythromycin. However, Posey-Dowty et al. teaches bone cement compositions containing preferably erythromycin as the antibiotic (Col. 3, lines 52-56). Lidgren and Posey-Dowty et al. are analogous art because they are from the same field of endeavor, namely that of bone cement compositions. At the time of the invention, a person of ordinary skill in the art would have found it obvious to use erythromycin as the antibiotic, as taught by Posey-Dowty et al., in the composition, as taught by Lidgren, and would have been motivated to do so because this antibiotic works well in these types of compositions to be released in a sustained high concentration (Col. 2, line 50).

Claims 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009) in view of Wenz (DE 20218668). For convenience, the citations below are taken from the English language equivalent US 2005/0287071.

Lidgren teaches a bone cement containing a liquid component containing a polymerizable substance and a powder component containing a plastic substance and an X-ray contrast medium (Abstract), such as iohexol (a non-polymerizable organoiodine compound) (Col. 2, lines 65-67).

Lidgren does not teach that the liquid portion or that the particulate polymer portion comprises at least one of hydroquinone, growth hormone, bone morphogenic protein, or vitamins. However, Wenz teaches a bone cement composition that contains, in either the liquid or powder component, a bone morphogenic protein compound (¶29). Lidgren and Wenz are

analogous because they are from the same field of endeavor, namely that of bone cement compositions. At the time of the invention, a person of ordinary skill in the art would have found it obvious to use a bone morphogenic protein, as taught by Wenz, in the composition, as taught by Lidgren, and would have been motivated to do so because it helps induce the formation of bone and cartilage.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lidgren (US 6,586,009) in view of Nies et al. (US 5,650,108).

Lidgren teaches a bone cement containing a liquid component containing a polymerizable substance and a powder component containing a plastic substance and an X-ray contrast medium (Abstract), such as iohexol (a non-polymerizable organoiodine compound) (Col. 2, lines 65-67).

Lidgren does not teach that the liquid portion is present in a range of from 25-45% by weight. However, Nies et al. teaches a bone cement composition comprising from 2 to 50% by weight of a liquid component (Col. 3, lines 30-35). Lidgren and Nies et al. are analogous art because they are from the same field of endeavor, namely bone cement compositions. At the time of the invention, a person of ordinary skill in the art would have found it obvious to use the above amount of liquid component, as taught by Nies et al., in the composition, as taught by Lidgren, and would have been motivated to do so in order to obtain the appropriate viscosity of the mixture (Col. 5, lines 55-60).

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 4-11, 13-17 and 42 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Angela C. Scott whose telephone number is (571) 270-3303. The examiner can normally be reached on Monday through Friday, 8:30am to 5:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on (571) 272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/  
Supervisory Patent Examiner, Art Unit 1796

/A. C. S./  
Examiner, Art Unit 1796  
March 12, 2010